



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2012-0230; FRL-9343-7]

FIFRA Scientific Advisory Panel; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 4-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review Problem Formulation for the Reassessment of Ecological Risks from the Use of Atrazine.

DATES: The meeting will be held on June 12–14, 2012, from 9:00 a.m. to approximately 5:30 p.m. and on June 15, 2012, from 9:00 a.m. to approximately 12:30 p.m.

Comments. The Agency encourages that written comments be submitted by May 29, 2012, and requests for oral comments be submitted by June 5, 2012. However, written comments and requests to make oral comments may be submitted until the date of the meeting, but anyone submitting written comments after May 29, 2012, should contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

Nominations. Nominations of candidates to serve as ad hoc members of FIFRA SAP for this meeting should be provided on or before [insert date 14 days from date of publication in the **Federal Register**].

Webcast. This meeting may be webcast. Please refer to the FIFRA SAP's website, <http://www.epa.gov/scipoly/sap> for information on how to access the webcast.

Please note that the webcast is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the meeting will continue as planned.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least 10 days prior to the meeting to give EPA as much time as possible to process your request.

ADDRESSES: The meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202.

Comments. Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0230, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2012-0230. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute.

Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

Nominations, requests to present oral comments, and requests for special accommodations. Submit nominations to serve as ad hoc members of FIFRA SAP, requests for special seating accommodations, or requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Sharlene R. Matten, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-0130; fax number: (202) 564-8382; e-mail address: matten.sharlene@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), FIFRA, and the Food Quality Protection Act of 1996 (FQPA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

If you have any questions regarding the applicability of this action to a particular entity, consult the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

When submitting comments, remember to:

1. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
2. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
3. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
4. Describe any assumptions and provide any technical information and/or data that you used.
5. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
6. Provide specific examples to illustrate your concerns and suggest alternatives.
7. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
8. Make sure to submit your comments by the comment period deadline identified.

C. How May I Participate in this Meeting?

You may participate in this meeting by following the instructions in this unit. To ensure proper receipt by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2012-0230 in the subject line on the first page of your request.

1. *Written comments.* The Agency encourages that written comments be submitted, using the instructions in **ADDRESSES**, no later than May 29, 2012, to provide FIFRA SAP the time necessary to consider and review the written comments. Written comments are accepted until the date of the meeting, but anyone submitting written comments after May 29, 2012, should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Anyone submitting written comments at the meeting should bring 30 copies for distribution to FIFRA SAP.

2. *Oral comments.* The Agency encourages that each individual or group wishing to make brief oral comments to FIFRA SAP submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** no later than June 5, 2012, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting and, to the extent that time permits, the Chair of FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment (e.g., overhead projector, 35 mm projector, chalkboard). Oral comments before FIFRA SAP are limited to approximately 5 minutes unless prior arrangements have been made. In addition, each speaker should bring 30 copies of his or her comments and presentation slides for distribution to the FIFRA SAP at the meeting.

3. *Seating at the meeting.* Seating at the meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc members of FIFRA SAP for this meeting.* As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas: Aquatic community ecology, surface water monitoring, water quality, environmental fate and transport, aquatic toxicity, plant toxicity, and statistics. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before [*insert date 14 days from date of publication in the Federal Register*]. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before this date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the panel and the expertise needed to address the Agency's charge to the panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal

department or agency except the EPA. Other factors considered during the selection process include availability of the potential panel member to fully participate in the panel's reviews, absence of any conflicts of interest or appearance of lack of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of lack of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on FIFRA SAP. Numerous qualified candidates are identified for each panel. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the panel. In order to have the collective breadth of experience needed to address the Agency's charge for this meeting, the Agency anticipates selecting approximately 10–12 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR part 2634, Executive Branch Financial Disclosure, as supplemented by the EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on the FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. The EPA will evaluate the candidates financial disclosure form to assess whether there are financial conflicts of interest, appearance of a lack of impartiality or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on FIFRA SAP. Those who are selected from the pool of

prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP website at <http://www.epa.gov/scipoly/sap> or may be obtained from the OPP Regulatory Public Docket at <http://www.regulations.gov>.

II. Background

A. Purpose of FIFRA SAP

FIFRA SAP serves as the primary scientific peer review mechanism of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act. FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health and the National Science Foundation. FIFRA, as amended by FQPA, established a Science Review Board consisting of at least 60 scientists who are available to the SAP on an ad hoc basis to assist in reviews conducted by the SAP. As a peer review mechanism, FIFRA SAP provides comments, evaluations and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications,

including training and experience, to provide expert advice and recommendation to the Agency.

B. Public Meeting

In 2006, EPA initiated a program called Registration Review to re-evaluate all pesticides on a regular cycle as part of the requirements of the FQPA. The program reviews each pesticide active ingredient every 15 years to make sure that as the ability to assess risks to human health and the environment evolves and as policies and practices change, all pesticide products in the marketplace can still be used safely. EPA will soon be reviewing atrazine as part of Registration Review.

An important step in the development of a risk assessment is the problem formulation. In a problem formulation, available information, including stressor sources and characteristics, exposure, ecological effects on plants and animals (*e.g.*, amphibians, fish, invertebrates, birds, and mammals), and characteristics of the ecosystem(s), is used to define assessment endpoints and to develop a preliminary understanding of potential risks (*i.e.*, develop a risk hypothesis and conceptual model) associated with the use of a pesticide. The problem formulation also serves as an opportunity to identify missing information/uncertainties that may limit the assessment and any assumptions that may be made in the absence of such data. This SAP meeting will focus on the proposed use of the Plant Assemblage Toxicity Index (PATI)-model, amphibians, and monitoring data all which are components of the problem formulation.

For the June 2012 SAP meeting, EPA will provide an overview of the current state of information on atrazine use, environmental fate (exposure), and ecological effects (toxicity) for assessing the potential ecological risk from the use of atrazine. Emphasis of

the SAP meeting will be directed at re-evaluation of micro/mesocosm studies and their impact on a PATI-derived level of concern (LOC) for aquatic plant communities and a strategy for using the PATI-derived LOC for identification of watersheds at risk. The strategy will employ adjustments to control for bias in atrazine concentrations from monitoring data according to sampling frequency. EPA will also include a review of atrazine studies with amphibians published in the open literature since the 2007 SAP on amphibians. This review will explore whether additional effects have been associated with exposure to atrazine and whether there is a relationship between effects reported across various studies and common study design elements. The SAP will be asked to comment on whether the review is thorough and whether uncertainties have been sufficiently characterized.

The Interim Reregistration Eligibility Decision (IRED) presented the results of the atrazine ecological risk assessment that identified the potential for community and population risk to sensitive aquatic species. Information in the revised IRED was based in part on the review and recommendations of the SAP which met in June 2003 to discuss the potential developmental effects of atrazine on amphibians. At that meeting, the Panel concurred with EPA's analysis that there was sufficient evidence to formulate a hypothesis that atrazine exposure may impact gonadal development in amphibians, but there were insufficient data at that time to confirm or refute the hypothesis. This led EPA to seek additional data through a data call-in (DCI) to reduce uncertainties regarding potential risk to amphibians.

In October 2007, EPA convened a second SAP meeting to evaluate available data on atrazine effects on gonadal development in amphibians. The SAP reviewed the

document entitled "White Paper on the Potential for Atrazine to Affect Amphibian Gonadal Development" and concurred with EPA that atrazine does not consistently affect amphibian gonadal development. Although the 2003 SAP indicated that African clawed frog (*Xenopus laevis*) was an appropriate test species given the extent to which the animal is used in amphibian developmental studies, the 2007 Panel concluded that a major uncertainty in the registrant data was the use of *X. laevis* as the test organism and the Panel recommended that additional studies were warranted on North American frog species. The SAP acknowledged though that there was uncertainty whether study methods for North American species were sufficiently developed or vetted to yield consistent results. Following the October 2007 SAP meeting, EPA determined that it was reasonable to reject the hypothesis that atrazine exposure can affect gonadal development. Consistent with the recommendations from the 2003 SAP, the Agency also determined, that given the absence of consistent effects and inability to reproduce effects used to support the hypothesis that atrazine affects amphibian development, there was no compelling reason to pursue additional testing with regard to the potential effects of atrazine on amphibian gonadal development. However, the Agency acknowledged that it would continue to monitor research on this subject as it becomes available.

Also as a condition of the 2003 reregistration, the atrazine registrants were required to develop a monitoring program to determine the extent to which atrazine concentrations associated with corn, sorghum, and sugarcane production may be exceeding levels that could cause effects to aquatic plant communities. Forty watersheds representing high atrazine use locations vulnerable to atrazine runoff were selected for monitoring using a stratified, random statistical survey design. Sampling within these

watersheds began in 2004 and is ongoing in selected watersheds. There are an additional 25 sites where monitoring began in 2010 to refine the approach for identifying vulnerable watersheds. EPA is evaluating the results of the atrazine monitoring program, also in part, to identify the characteristics of those watersheds that resulted in atrazine exposures exceeding the Agency's LOC and to extrapolate those results to other non-monitored locations to determine where atrazine concentrations may exceed the LOC.

In December 2007, EPA presented to the SAP the use of the Comprehensive Aquatic Systems Model (CASM) as a tool to determine an LOC that relates time variable monitoring data to effects identified in a series of microcosm and mesocosm studies. The SAP recommended that EPA:

1. Work with the CASM-Atrazine model to make the population time series more realistic;
2. Provide a better validation of this model, and
3. Conduct a more comprehensive sensitivity analysis.

In May 2009, EPA presented a simpler alternative to the CASM-based approach to relate surface water monitoring data to the microcosm and mesocosm data, called the PATI. Other issues presented at this meeting included a revised assessment of the microcosm and mesocosm exposure profiles, an update on the ecological monitoring program results, interpretation of the monitoring results with PATI, identification of the watershed factors driving atrazine runoff, and extrapolation of those results to the entire atrazine use area to identify other areas where atrazine exposures may exceed the LOC. The 2009 Panel suggested that both the CASM-Atrazine model (presented by Syngenta) and PATI were suitable assessment tools for atrazine. The PATI model was

recommended by the SAP as a generic assessment tool for developing an LOC, while CASM was recommended by the SAP as a site-specific assessment tool because of the need for extensive site-specific data. The Panel noted that a limitation in the CASM model is the lack of understanding of the sensitivity of model predictions with correlations among model parameters. The SAP recommended that EPA re-evaluate the meso/microcosm data set for study quality and concentration-specific effects, and provided additional citations for meso/microcosm studies to consider including in the assessment. They also recommended using a probabilistic approach to determine the LOC. The SAP concurred with EPA's incorporation of depth to impervious layer and slope to identify vulnerable watersheds for atrazine runoff as part of the atrazine vulnerability index. They also cautioned EPA that several watershed factors such as atrazine use intensity and rainfall are temporally dependent and, therefore, should not be considered minimum criteria in the vulnerability index.

C. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, related supporting materials, charge/questions to FIFRA SAP, FIFRA SAP composition (i.e., members and ad hoc members for this meeting), and the meeting agenda will be available at least 15 days prior to the meeting. In addition, the Agency may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available electronically, at <http://www.regulations.gov> and the FIFRA SAP homepage at <http://www.epa.gov/scipoly/sap>.

FIFRA SAP will prepare meeting minutes summarizing its recommendations to the Agency approximately 90 days after the meeting. The meeting minutes will be

posted on the FIFRA SAP website or may be obtained from the OPP Regulatory Public Docket at *<http://www.regulations.gov>*.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: March 27, 2012

Frank Sanders,

Director, Office of Science Coordination and Policy.

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